

REMARKS

Applicant has received and carefully reviewed the Office Action mailed October 29, 2009. Claims 1-9, 13-15, 23-32, 37, 39-44, 50-54, and 60 are pending. Reconsideration and allowance of the pending claims are respectfully requested.

Improper Final Action

The final Office Action mailed October 29, 2009 appears to be a substantial duplicate of the Office Action mailed February 20, 2009, as evidenced by the rejection of claims that were previously canceled, and the repeated reference to Applicant's arguments of 9/4/2007. Substantial prosecution has occurred since that date. The only change to the final Office Action appears to be a slight change to the language of a single sentence in the Response to Arguments section on pages 5-6, and the added sentence, "[i]t is contended that the device of the reference can be used in the manner as recited in the claims." The Examiner has not, however, provided any support for this assertion, as discussed below. A personal interview was conducted on June 2, 2009, and Applicant's last response, mailed June 22, 2009 contained significant amendments and comments in accordance with what was discussed in the personal interview. Applicant has made a good faith effort to advance prosecution with the personal interview and substantial amendment filed June 22, 2009. The mailing of essentially a copy of a previous Office Action, without any substantive comments regarding the recently amended claims, appears to be an error. Applicant respectfully requests the finality of the Office Action be withdrawn and a complete response to Applicant's amendments and arguments be made by the Office.

Double Patenting

Claims 1-10, 13-20, 23-34, 37-42, 44-46, 49-52, 54-56, 59-62, and 64-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 1, 3, 14, 20, 33 of US Patent No. 6,361,488. Applicant wishes to point out that claims 10, 16-20, 33, 34, 38, 45, 46, 49, 55, 56, 59, 61, 62, and 64-68 were canceled in the response mailed June 22, 2009. As stated in the previous response, Applicants do not concede the correctness of the rejection, however in the interest of advancing prosecution, a

Terminal Disclaimer will be provided when the claims are otherwise indicated as being allowable.

Rejection under 35 U.S.C. § 102(b)

Claims 1-10, 13-20, 23-34, 37-42, 44-46, 49-52, 54-56, 59-62, and 64-68 are rejected as being anticipated by Graber et al. (US 5,370,647). Applicant wishes to point out that claims 10, 16-20, 33, 34, 38, 45, 46, 49, 55, 56, 59, 61, 62, and 64-68 were canceled in the response mailed June 22, 2009. Applicant notes that the rejection was made under 35 U.S.C. § 102, and thus requires the reference teach the identical invention. Graber et al. do not appear to teach any structure that could be considered identical to the structure recited in the claims. As discussed below, the Examiner does not appear to have considered the amendments to the claims made in the June 22, 2009 response, but has instead merely repeated the identical rejections from a previous Office Action. The Examiner has not responded to any of Applicant's arguments made in the June 22, 2009 response. Applicant respectfully requests that if the rejections are maintained, the Examiner provide a proper response with comments regarding the amended claims and the arguments set forth below.

Independent claim 1, as previously amended, recites:

1. A system enabling minimally invasive procedures at a surgical location at or near the spine of a patient, said system comprising:

an elongate body having an inner surface defining a passage extending through the elongate body and through which surgical instruments can be inserted to the surgical location, said elongate body capable of having a configuration when inserted within the patient wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location, said elongate body having a proximal portion and a distal portion, wherein the proximal portion is pivotable relative to the distal portion; and

a support arm configured to support the proximal portion of the elongate body hands-free outside the patient when the distal portion is inserted at the surgical location, the support arm configured to pivot the proximal portion relative to the distal portion, and to support and maintain the proximal portion in the pivoted position.

The Examiner does not appear to have considered the amended claim in formulating the rejection. Graber et al. do not appear to teach the claimed structure. The Examiner asserts

that Graber et al. teach a support arm/cannula 4 supporting elongate body 10. Graber et al. teach:

cannula 4 is introduced into the abdominal cavity 2 to provide the passageway for the laparoscopic instruments necessary to perform any particular laparoscopic surgical procedure... The tissue and organ extractor 10 is then introduced through the cannula 4 into the abdominal cavity 2...The surgeon then removes the cannula 4, tissue and organ extractor 10, forceps 102 and tissue or organ 100 simultaneously through the small puncture orifice in the abdominal wall through which the cannula 4 was originally inserted.

See column 6, lines 23-52. Graber et al. thus appear to teach the surgeon holding the cannula 4 as the organ extractor 10 is inserted, the tissue specimen is grasped, and then the surgeon removing all instruments together with the tissue specimen. Graber et al. do not appear to teach any structure that supports a proximal portion of the extractor hands-free outside the patient when the distal portion is inserted at the surgical location, where the support arm is configured to pivot the proximal portion relative to the distal portion, and to support and maintain the proximal portion in the pivoted position, as recited in independent claim 1. Graber et al. thus cannot be deemed to teach the identical structure recited in the claim, as is necessary for anticipation. Further, there is no motivation for one of ordinary skill in the art to modify Graber et al. to achieve the claimed structure.

In the Response to Arguments section on page 5, the Examiner asserts that the claims provide some functional language but does not clearly provide any structural limitations to distinguish the claimed invention over the prior art references. Applicant respectfully disagrees. MPEP 2173.05(g) states:

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.

Applicant submits that the functional language recited in independent claim 1 does convey a difference in the claimed structure over that of Graber et al. Graber et al. does not appear to have any structure that would support the proximal portion of the device of Graber et al. hands-free outside the patient. Further, Graber et al. does not appear to teach any structure that is configured to pivot the proximal portion relative to the distal portion and to support and

maintain the proximal portion in the pivoted position, as recited in claim 1. The Examiner merely recites that "[i]t is contended that the device of the reference can be used in the manner as recited in the claims." The Examiner has not, however, provided any indication of what structure would provide the function or how one of ordinary skill would use the device of Graber et al. in the manner recited in the claims.

MPEP § 2131

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipse dixit* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicant submits that Graber et al. does not teach each and every elements as set forth in claim 1. Further, if the Examiner is considering the specific elements recited in the claims to be inherent in Graber et al., Applicant submits that there is no basis for such an interpretation. MPEP § 2112(IV) states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)...

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

(Emphasis added). Applicant submits that the claimed elements, in particular the support arm configured to support the proximal portion of the elongate body hands-free outside the patient when the distal portion is inserted at the surgical location, where the support arm is configured to pivot the proximal portion relative to the distal portion, and to support and maintain the proximal portion in the pivoted position, are not necessarily present in Graber et al. It appears the Examiner is asserting that the claimed elements could be achieved by somehow modifying the system of Graber et al., which is not a proper basis for anticipation.

Independent claim 23, as previously amended, recites:

23. A device for providing access to a first location adjacent the spine of a patient, comprising:

an elongate body having a proximal end and a distal end and a passage extending through the elongate body through which surgical instruments can be delivered, said elongate body being enlargeable such that the passage at a distal location is larger than the passage at a proximal location; and

a support arm operably connected to the proximal end of the elongate body, the support arm extending generally transverse to an axis defined along the passage of the elongate body between the proximal and distal ends, the support arm configured to support and position the elongate body outside of the patient when the device is applied to the patient, the support arm configured such that a user may place the elongate body in a desired position relative to the patient, and the support arm maintains the elongate body in the desired position without being held by a user.

The Examiner has not addressed the above previous amendment to claim 23. Applicant submits that Graber et al. do not appear to teach such a structure. Further, the functional language recited in independent claim 23 does convey a difference in the claimed structure over that of Graber et al. The Examiner equates the cannula 4 of Graber et al. with the claimed support arm. As discussed above, Graber et al. appear to teach a system in which the surgeon holds the cannula 4 as the extractor 10 is manipulated through the cannula to extract the tissue specimen. Graber et al. do not appear to teach or suggest a support arm configured such that a user may place the elongate body in a desired position relative to the patient, and the support arm maintains the elongate body in the desired position without being held by a user, as recited in claim 23. Further, there is no motivation for one of ordinary skill in the art to modify Graber et al. to achieve the claimed structure.

Independent claim 26, as previously amended, recites:

26. A system enabling minimally invasive procedures at a surgical location at or near the spine of a patient, said system comprising:

an elongate body having an inner surface defining a passage extending through the elongate body and through which surgical instruments can be inserted to the surgical location, said elongate body being expandable from a first configuration for insertion into a patient to a second configuration when inserted within the patient wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location; and

a first support arm configured to support the elongate body outside the patient when the system is applied to the patient the support arm configured to move the elongate body and to maintain the elongate body in a desired position relative to the patient without being held by a user; and

a second support arm configured to support a viewing device without being held by a user, the second support arm coupled to the first support arm.

The Examiner has again not addressed the claim as previously amended. Graber et al. do not appear to teach such a structure. Further, the functional language recited in independent claim 26 does convey a difference in the claimed structure over that of Graber et al. Graber et al. appear to teach a system in which separate, non-coupled cannulas 4 and 5 are used, with the extractor 10 being inserted through one cannula 4, and a laparoscope being inserted through a auxiliary cannula 5. Thus, even if one were to equate the cannulas 4 and 5 of Graber et al. with the claimed first and second support arms, the claimed structure is distinguished from Graber et al. The Examiner asserts that “2nd support arm 5 is coupled to (formed a pair to or combined to) 1st support arm 4.” Applicants respectfully disagree. While Graber et al. appear to teach using cannulas 4 and 5 together in the same surgical procedure, they are not taught as being coupled, but rather are used at separate and distinct locations, as clearly shown in Figure 4. Applicants submit that the separate cannulas 4 and 5 of Graber et al. cannot be considered to be coupled, as recited in the claim. Applicants submit that the ordinary and common use of the word “coupled” would not be interpreted by one of ordinary skill in the art to describe the separate cannulas 4 and 5 taught by Graber et al. to be inserted at separate and spaced-apart locations, as shown in Figure 4. Additionally Graber et al. do not appear to teach the separate cannulas 4 and 5 as being structured to support the elongate body and viewing device, respectively, without being held by a user, as recited in the claim. Graber et al. thus cannot be seen to teach each and every element of the structure recited in independent

claim 26 or the claims dependent thereon. Further, because Graber et al. specifically teach the use of separate cannulas to visualize the interior of the abdominal cavity, Graber et al. appear to teach away from modifying their system to achieve the structure as claimed.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 26, 27, 30, 31, 37, 40, 41, and 43 are rejected as being anticipated by Bonutti (US 5,197,971). As discussed above, the Examiner has not addressed the previously amended claims and has not provided any response to the specific arguments set forth in the June 22, 2009 response. As discussed below, Bonutti fail to teach the identical structure recited in the claims.

The Examiner asserts that Bonutti teach a 1st support arm 20, and 2nd support arm 30 for supporting a viewing device. Applicants respectfully disagree. Bonutti appear to teach a "retractor 10 includes a retractor body 12, a retractor sleeve 14, and a nut 16. The hollow tubular retractor body 12 (FIG. 3) includes a central portion 18, a widened distal end portion 20, and a threaded proximal end portion 22." See column 4, lines 39-43. Bonutti also teaches "nut 16 (FIG. 4) includes a body portion 30 having a threaded bore 32 for receiving the threaded end portion 22 of the retractor body 12." See column 4, lines 58-60. Applicants submit that Bonutti fails to teach a device having first and second support arms as recited in the claims. The widened distal end portion 20 of the retractor of Bonutti cannot be considered a support arm as recited in the claims because Bonutti appear to teach the distal end portion 20 of the retractor as being inserted into the patient during a procedure, as shown in FIGS. 11 and 13. Bonutti appears to teach a retractor with a threaded nut functioning as a handle. Bonutti further teaches, "handles 34 can be grasped by a surgeon to rotate the nut 16, and to manipulate the retractor 10 as a whole." Bonutti thus appears to teach a nut structure that is held by the surgeon during the procedure. Bonutti thus fails to teach the identical structure recited in independent claim 26 and the claims dependent thereon. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 11, 12, 21, 22, 35, 36, 43, 47, 48, 53, 57, 58, and 63 are rejected as being unpatentable over Graber et al. Applicant wishes to point out that claims 11, 12, 21, 22, 35,

36, 47, 48, 57, 58, and 63 were previously canceled, leaving only claims 43 and 53 of this list of rejected claims actually pending. The inclusion of numerous canceled claims in the rejection suggests the Examiner has not fully considered Applicant's previous response filed June 22, 2009. For at least the reasons set forth above, Graber et al. do not appear to teach each and every element of the independent claims from which the above claims depend. Further, there is no motivation or suggestion for one of ordinary skill in the art to modify the device of Graber et al. to achieve the claimed structure. Reconsideration and withdrawal of the rejection are respectfully requested.

Reconsideration and reexamination are respectfully requested. It is submitted that, in light of the above remarks, all pending claims are now in condition for allowance. If a telephone interview would be of assistance, please contact the undersigned attorney.

Respectfully Submitted,
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By his Attorney,

Date: _____

12/1/09



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